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Opinion

Pediatric Covid Protections Limited by the Medical Police State

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On Monday, August 23, 2021, the Food and Drug Administration (FDA) approved Pfizer's covid vaccine for general use. The legal reality is, that after general release of any drug by the FDA and under normal circumstances, this would allow physicians to prescribe and utilize the drug in Americans of any age, including children. We know CDC data documents hundreds of thousands of childhood covid cases and hundreds of deaths with rising numbers, while hopefully children are returning to school exposed to increasing risks. Although Federal laws prohibit age and disability discrimination, children and especially "at risk" children < 12 years are not being fully offered any of the treatments authorized under the emergency use authority (EUA) to mitigate the covid scourge. The Pfizer vaccine was released yesterday for Americans 12 years of age and >40 KG. In 2002, the Association of American Physicians and Surgeons sued in Federal Courts, which determined the "FDA Does Not Have The Authority to Require Pediatric Testing of Drugs". This ruling allows all approved drugs to be used in children as "off label", when appropriately prescribed and especially with informed consent [1].

Multiple drugs have been released under EUA to fight the covid scourge, where the lack of full FDA approval restricts use to designated Ages> 12. Because of the dangers from covid, many physicians have spoken out and prescribed drugs "off label" for prevention, treatment and covid prophylaxis, especially as early on, no approved therapies existed. These drugs have been withheld and shortages prolonged. Now, increasingly restrictions on media to eliminate non-mainstream opinion and data under government pressures, has mounted. Recently, physicians have been threatened by the Federation of State Medical Boards (FSMB), a nonprofit that asserts it represents all U.S. state medical boards, stating any clinicians who creates or spreads vaccine misinformation or disinformation risks disciplinary action by state medical boards, including suspension or revocation of their medical license. Definitions of misinformation and disinformation remain obscure [2]. Such action is chilling for physicians treating children, who typically receive most medications outside FDA approvals. With the release of Pfizer vaccine as FDA approved, off label use in children is a just and historically appropriate consideration, yet remains unaddressed and will be withheld due to overwhelming threats against physicians to remain within government guideline and in spite of significant historical precedent. Other therapies currently used on adults may continue to remain withheld, potentially in the face of severe childhood disease, should such threats against physicians prohibit treatment "in their best medical judgement".

This government overreach into the physician-patient relationship occurs in the midst of the now fourth covid "surge", while prevention and therapy for all Americans under age 12 continues to be inadequately addressed by government expert policy. These experts continue to blame unvaccinated American Adults for this current 'surge" in cases while arbitrarily prohibiting childhood vaccination. Children return to schools, where state laws typically mandate complete vaccination proof for a multitude of infectious agents, specifically virus like measles, mumps and others and without comparable covid protection. Our government and media continue to strongly push for universal vaccination (without our 50 million children being considered in the equation) to create a "herd immunity" in this country. However, CDC data indicate 52% of adults are fully vaccinated and 120 million have had covid-which should assure herd immunity. Given the rapid transformation of Covid virus into variants, reinfections of the vaccinated, open boarders, international travel and the impossibility to vaccinate the whole world at one time, we must consider that virus transformation,, current CDC data and short term reinfection rates make this proposal spurious. Masks and social distancing have not proven effective as multiple "surges" reoccur. Yet the 50 million Americans< age 12 cannot be effectively protected out of physician fear from the Medical Police State of the FSMB and State Medical Boards, insuring all "unapproved" therapy or drug use remains withheld, due to licensing fears.

Governor Abbott of Texas and Ex President Trump received treatments after simply testing positive for covid, including modern bioengineered immunoglobulins. One therapy other than

vaccination deserves immediate specific consideration by parents and physicians at this time: Administration of convalescent plasma (CCP) infusions for protection and treatment. This antibody-packed plasma from recovered patients after COVID-19 was also rapidly approved for use by the FDA under EUA one year ago on August 23, 2020. As plasma concentrate administration has been used for decades in transfusion therapy for multiple diseases and with increasing safety, the risk in children is well known, unlike that of new Covid vaccines. Of particular note is that the FDA's EUA did not place restrictions on the age of the patient in any way, stating further: "Based on results from prior studies, the safety profile of CCP appears comparable to that of plasma transfusion in general. Considering this safety profile, it is reasonable to believe that the known and potential benefits of high titer CCP outweigh the known and potential risks when used for the early treatment of hospitalized COVID-19 patients [3]." The facts that newborns are known to be protected by maternal transfer of these antibodies for 3-6 months from many infections and that the EUA for synthetic covid antigens was specifically issued for early outpatient treatment, suggests CCP would be a reasonable consideration also for early out-patient prophylactic and preventative treatment in high risk children and those testing positive, similar to Governor Abbott of Texas. The fact that this product remains under EUA without full FDA approval presents a barrier to full "off label" utilization to the benefit of non- hospitalized Americans and children, as physicians remain intimidated by licensing boards. The early pre-hospital administration appears most beneficial and may also be an immediately effective preventative (unlike vaccination, which requires weeks) offering 3-6 months of protection for high risk children in families with recent exposure or positive covid tests, long enough to bridge the infection period. Parents should consider discussions advocating childhood care with their physician and legislators now.

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